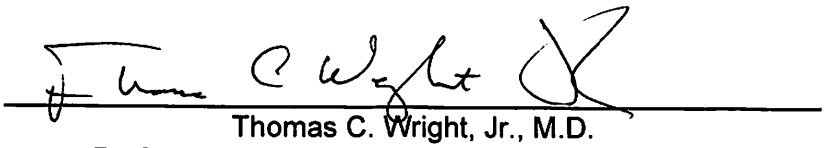
EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO WAVE I	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

EXPERT REPORT OF THOMAS C. WRIGHT JR., M.D.

Prepared by



Thomas C. Wright, Jr., M.D.
Professor Emeritus of Pathology and Cell Biology
Columbia University

March 1, 2016

Background and Qualifications

I, Thomas C Wright, Jr. MD, am a board certified Anatomic Pathologist with 28 years of experience in gynecological, obstetrical, and cytological pathology. From 1989 - 2011 I was an attending pathologist in Division of Gynecological, Obstetrical, and Cytological Pathology at Columbia University, New York, NY and from 1998-2011 I was the Director of the Division of Gynecological, Obstetrical, and Cytological Pathology at Columbia University. I am currently a Professor Emeritus of Pathology and Cell Biology at Columbia University and work as a gynecological and cytological pathologist at Enzo Clinical Laboratories, in Farmingdale, NY. I actively participate as a gynecological pathologist for multiple research studies and clinical trials. During my work as a gynecological pathologist I evaluate explanted mesh material from the vagina.

In addition to my extensive experience in gynecologic pathology, I also have specific experience evaluating host tissue responses to implanted materials in the female gynecologic tract. From 1997 to 2008 I served as the expert gynecologic pathologist for Conceptus. In that role, I evaluated the host tissue response to a variety of different biocompatible materials. I then served as the study pathologist for the company's pivotal FDA trial, as well as subsequent post-approval study. During the course of this work I evaluated and quantified host tissue responses and ingrowth of fibrosis in implanted intra-fallopian devices.

Reason for Using Implanted Polypropylene Mesh to Strengthen Vaginal Tissues in Women with Pelvic Organ Prolapse

Pelvic organ prolapse (POP) is reported to affect one in three women and each year in the U.S. 200,000 women undergo surgical correction of pelvic organ prolapse.[1,2] Traditional surgical correction of POP has a relatively high failure rate. Up to 70% of women who undergo traditional surgical repair for pelvic organ prolapse are reported to have recurrent prolapse and 29% of surgically managed women require reoperation.[3,4] Part of the reason for the high rate of recurrent prolapse after surgical correction is that like abdominal hernia patients, POP prolapse patients have weakened connective tissue which is more susceptible to forming architectural defects. Hernia patients have been found to have a different fibroblast phenotype than do non-hernia patients and these altered fibroblasts produce collagen that is both quantitatively and qualitatively abnormal. In most patients collagen consists primarily of Type I and Type III

collagen fibrils that are produced in a 4:1 ratio. Hernia patients over express Type III collagen type.[5,6] The excess in Type III collagen inhibits cross-linking of Type I collagen and cross-linking between Type I and Type III collagen. This results in collagen fibers that are inherently thinner and weaker and which undergo lysis more readily. Similar alterations in Type I to Type III collagen ratios have been found in women with POP.[7] In addition to collagen alterations of women with POP, the amount of smooth muscle actin (SMA) in the muscularis of the vaginal wall is reduced.[8] The finding of alterations in the connective tissue of the vaginal wall in women with POP suggests that an inherent laxity or weakness of the connective tissue contributes to POP. Therefore synthetic mesh materials were introduced to reinforce weakened native tissues during pelvic reconstructive surgery in women with pelvic prolapse of the bladder or rectum in order to improve clinical outcomes and reduce surgical failure rates.[3] Synthetic mesh implants have been shown to be stronger and more resistant than biological tissue.[9,10] A number of randomized controlled trials comparing outcomes after mesh repair surgery versus traditional surgery and many of these have shown that mesh-based repairs have higher success rates than traditional surgery.[11-13]

Inflammatory Response and Foreign Body Response to Foreign Materials

Although the host inflammatory and foreign body response to implanted synthetic foreign material follows a fairly typical sequence of events, the specifics of the response may vary considerably depending on the composition of the foreign material.[14] In addition, the host response will vary somewhat depending on the site and the species in which a synthetic foreign material is implanted. Nevertheless, in general, host inflammatory and foreign body responses are comparable between sites and the typical species utilized for biocompatibility and tissue response studies.

Acute Phase of the Response

Implanted foreign material very quickly get covered by a layer consisting of adsorbed host proteins. This process follows a fixed hierarchical pattern that is termed the *Vroman effect* after the person who described it. Initially, low molecular weight proteins like albumin that have the highest mobility are adsorbed to the foreign material. Subsequently, complex higher molecular weight, and therefore less mobile, proteins such as fibrinogen, immunoglobulins, and